

General

Guideline Title

ACR Appropriateness Criteria® breast cancer screening.

Bibliographic Source(s)

Mainiero MB, Bailey L, D'Orsi C, Green ED, Holbrook AI, Lee SJ, Lourenco AP, Moy L, Sepulveda KA, Slanetz PJ, Trikha S, Yepes MM, Newell MS, Expert Panel on Breast Imaging. ACR Appropriateness Criteria® breast cancer screening. Reston (VA): American College of Radiology (ACR); 2016. 7 p. [52 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Mainiero MB, Lourenco A, Mahoney MC, Newell MS, Bailey L, Barke LD, D'Orsi C, Harvey JA, Hayes MK, Huynh PT, Jokich PM, Lee S, Lehman CD, Mankoff DA, Nepute JA, Patel SB, Reynolds HE, Sutherland ML, Haffty BG, Expert Panel on Breast Imaging. ACR Appropriateness Criteria® breast cancer screening. [online publication]. Reston (VA): American College of Radiology (ACR); 2012. 5 p. [28 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

ACR Appropriateness Criteria®

Clinical Condition: Breast Cancer Screening

<u>Variant 1</u>: High-risk women: women with a BRCA gene mutation and their untested first-degree relatives, women with a history of chest irradiation between the ages of 10 and 30, women with 20% or greater lifetime risk of breast cancer.

Radiologic Procedure	Rating	Comments	RRL*
Mammography screening	9	Beginning at age 25-30 or 10 years before age of first-degree relative with breast cancer or 8 years after radiation therapy, but not before age of 25. Mammography and MRI are complementary examinations; both should be performed.	₩₩
Digital Matingoboadenthe2;3 descrathenot	appropriate; 4,5,6 N	Taßdginaippatprijat25-730,9rUsundhysalppkopriagteof first-	*Relative Radiation Level

Radiologic Procedure	Rating	degree relative with breast cancer or 8 years after radiation therapy, but not before age of 25.	RRL*
		Mammography and MRI are complementary examinations; both should be performed.	
MRI breast without and with IV contrast	9	Mammography and MRI are complementary examinations; both should be performed.	О
US breast	6	If patient cannot have MRI.	О
FDG-PEM	2		***
Tc-99m sestamibi BSGI	2		***
MRI breast without IV contrast	1		О
Rating Scale: 1,2,3 Usually not	appropriate; 4,5,6	May be appropriate; 7,8,9 Usually appropriate	*Relative Radiation Level

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

<u>Variant 2</u>: Intermediate-risk women: women with personal history of breast cancer, lobular neoplasia, atypical ductal hyperplasia, dense breasts, or 15% to 20% lifetime risk of breast cancer.

Radiologic Procedure	Rating	Comments	RRL*
Mammography screening	9	Mammography and MRI are complementary examinations. MRI should not replace mammography.	⊕ ⊕
Digital breast tomosynthesis screening	9	Mammography and MRI are complementary examinations. MRI should not replace mammography.	\$ \$
MRI breast without and with IV contrast	7	Mammography and MRI are complementary examinations. MRI should not replace mammography.	О
US breast	5		О
FDG-PEM	2		***
Tc-99m sestamibi BSGI	2		***
MRI breast without IV contrast	1		О
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

<u>Variant 3</u>: Average-risk women: women with <15% lifetime risk of breast cancer, breasts not dense.

Radiologic Procedure	Rating	Comments	RRL*
Mammography screening	9		€ €
Digital breast tomosynthesis screening	9		€ €
MRI breast without and with IV contrast	3		О
US breast	2		О
MRI breast without IV contrast	1		О
FDG-PEM	1		8888
Tc-99m sestamibi BSGI	1		***
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Summary of Literature Review

Mammography

Mammography is the only method of screening for breast cancer shown to decrease mortality. Annual screening mammography is recommended starting at: 1) age 40 for general population; 2) age 25 to 30 for BRCA (BReast CAncer 1) carriers and untested relatives of BRCA carriers; 3) age 25 to 30 or 10 years earlier than the age of the affected relative at diagnosis (whichever is later) for women with a first-degree relative with premenopausal breast cancer or for women with a lifetime risk of breast cancer ≥20% on the basis of family history; 4) 8 years after radiation therapy but not before age 25 for women who received mantle radiation between the ages of 10 and 30; and 5) any age for women with biopsy-proven lobular neoplasia, atypical ductal hyperplasia (ADH), ductal carcinoma in situ (DCIS), or invasive breast cancer. However, mammography alone does not perform as well as mammography plus supplemental screening in certain subsets of women, particularly those with a genetic predisposition to the disease and those with dense breasts. Therefore, supplemental screening is recommended in selected high-risk populations.

Digital Breast Tomosynthesis

Digital breast tomosynthesis (DBT) can address some of the limitations encountered with standard mammographic views. In addition to planar images, DBT allows for creation and viewing of thin-section reconstructed images that may decrease the lesion-masking effect of overlapping normal tissue, and reveal the true nature of potential false-positive findings without the need for recall. Several studies confirm that in a screening setting, cancer detection rate is increased with use of DBT compared to two-dimensional (2-D) mammography alone. Additionally, the rate of recall for benign findings (false positives) can be decreased. Some authors found these advantages to be especially pronounced in women under age 50, in those with dense breasts, and with lesion types including spiculated masses and asymmetries. Interpretation time for DBT images is greater than for standard mammography. Additionally, dose is increased if standard 2-D images are obtained in addition to DBT images. However, synthesized reconstructed images (a virtual planar image created from the tomographic data set) may replace the need for a 2-D correlative view; and current data suggests that these synthetic images perform as well as standard full-field digital images.

Magnetic Resonance Imaging

Breast magnetic resonance imaging (MRI) in high-risk women has been shown to have a higher sensitivity than mammography, and the combination of mammography and MRI in this population has the highest sensitivity. In a high-risk population, MRI and mammography combined have a higher sensitivity (92.7%) than ultrasound (US) and mammography combined (52%). Therefore, in high-risk women for whom supplemental screening is indicated, MRI is recommended when possible.

Screening high-risk women with breast MRI is cost-effective and the cost-effectiveness of screening MRI increases with increasing breast cancer risk. The American Cancer Society recommends screening breast MRI in certain high-risk women, and the American College of Radiology (ACR) and Society of Breast Imaging endorse those recommendations. Screening MRI is recommended in women with BRCA gene mutations and their untested first-degree relatives as well as women with a lifetime risk of breast cancer of \sim 20% or greater. Also included in this high-risk group are women who have received radiation therapy to the chest between the ages of 10 and 30 as well as women with other genetic syndromes that increase the risk of breast cancer (e.g., Li Fraumeni syndrome). For other women with an intermediate risk of breast cancer, such as those with a lifetime risk of 15% to 20%, a personal history of breast cancer, or a history of lobular neoplasia or ADH, the use of screening MRI is an area of ongoing investigation. However, recent literature supports the use of screening MRI in addition to mammography in patients with a personal history of breast cancer and lobular neoplasia.

Ultrasound

Screening US is indicated in high-risk patients who cannot tolerate MRI. Supplemental screening with US for women with intermediate risk and dense breasts is an option to increase cancer detection. However, hand-held US screening by the radiologist has a high false-positive rate and is time-consuming. Therefore, this may not be a cost-effective practice. The balance between cancer detection and the risk of a false-positive result should be considered by women and their health care providers when considering the use of screening US or other ancillary screening examinations.

Other Imaging Modalities

There is insufficient evidence to support the use of other imaging modalities such as thermography, breast-specific gamma imaging (BSGI), positron emission mammography (PEM), or optical imaging for breast cancer screening. Radiation dose from BSGI and PEM are 15 to 30 times higher than the dose of a digital mammogram, and they are not indicated for screening in their present form.

Summary of Recommendations

• For high-risk women, annual screening mammography and contrast-enhanced MRI are both indicated. US can be used for patients with

contraindications to MRI.

- For intermediate-risk women, annual screening mammography is indicated. Contrast-enhanced MRI may be indicated in some patients.
- For average-risk women, annual screening mammography is indicated.

Abbreviations

- BRCA, BReast CAncer 1 gene
- BSGI, breast-specific gamma imaging
- IV, intravenous
- FDG-PEM, fluorine-18-2-fluoro-2-deoxy-D-glucose positron-emission mammography
- MRI, magnetic resonance imaging
- Tc-99m, technetium-99 metastable
- US, ultrasound

Relative Radiation Level Designations

Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range	
O	0 mSv	0 mSv	
❤	<0.1 mSv	<0.03 mSv	
₩₩	0.1-1 mSv	0.03-0.3 mSv	
₩₩	1-10 mSv	0.3-3 mSv	
♥♥♥	10-30 mSv	3-10 mSv	
\$\$\$\$\$	30-100 mSv	10-30 mSv	

^{*}RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (e.g., region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as "Varies."

Clinical Algorithm(s)

Algorithms were not developed from criteria guidelines.

Scope

Disease/Condition(s)

Breast cancer

Guideline Category

Prevention

Screening

Clinical Specialty

Family Practice

Internal Medicine

Nuclear Medicine

Intended Users

Advanced Practice Nurses

Health Plans

Hospitals

Managed Care Organizations

Physician Assistants

Physicians

Obstetrics and Gynecology

Preventive Medicine

Oncology

Radiology

Students

Guideline Objective(s)

Utilization Management

To evaluate the appropriateness of imaging procedures for breast cancer screening

Target Population

- Women at high risk of breast cancer
- Women at intermediate risk of breast cancer
- Women at average risk of breast cancer

Interventions and Practices Considered

- 1. Mammography screening
- 2. Digital breast tomosynthesis screening
- 3. Magnetic resonance imaging (MRI), breast
 - Without and with intravenous (IV) contrast
 - Without IV contrast
- 4. Ultrasound (US), breast
- 5. Fluorine-18-2-fluoro-2-deoxy-D-glucose positron-emission mammography (FDG-PEM)
- 6. Technetium-99 metastable (Tc-99m) sestamibi breast-specific gamma imaging (BSGI)

Major Outcomes Considered

- Breast cancer mortality
- Breast cancer detection rate
- False-positive and false-negative ratios
- Diagnostic accuracy, sensitivity, and specificity of imaging procedures for breast cancer diagnosis
- Recall rates
- Biopsy rates

• Risks of radiation-induced cancer from imaging procedures

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search Summary

Of the 28 citations in the original bibliography, 27 were retained in the final document. Articles were removed from the original bibliography if they were more than 10 years old and did not contribute to the evidence or they were no longer cited in the revised narrative text.

A literature search was conducted in July 2015 to identify evidence for the *ACR Appropriateness Criteria® Breast Cancer Screening* topic. Using the search strategy described in the literature search companion (see the "Availability of Companion Documents" field), 161 articles were found. Twenty-five articles were used in the topic. One hundred thirty-six articles were not used due to either poor study design, the articles were not relevant or generalizable to the topic, or the results were unclear, misinterpreted, or biased.

See also the American College of Radiology (ACR) Appropriateness Criteria® literature search process document (see the "Availability of Companion Documents" field) for further information.

Number of Source Documents

Of the 28 citations in the original bibliography, 27 were retained in the final document. The new literature search conducted in July 2015 identified 25 articles that were used in the topic.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Definitions of Study Quality Categories

Category 1 - The study is well-designed and accounts for common biases.

Category 2 - The study is moderately well-designed and accounts for most common biases.

Category 3 - The study has important study design limitations.

Category 4 - The study or source is not useful as primary evidence. The article may not be a clinical study, the study design is invalid, or conclusions are based on expert consensus.

The study does not meet the criteria for or is not a hypothesis-based clinical study (e.g., a book chapter or case report or case series description);

Or

The study may synthesize and draw conclusions about several studies such as a literature review article or book chapter but is not primary

evidence;

Or

The study is an expert opinion or consensus document.

Category M - Meta-analysis studies are not rated for study quality using the study element method because the method is designed to evaluate individual studies only. An "M" for the study quality will indicate that the study quality has not been evaluated for the meta-analysis study.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The topic author assesses the literature then drafts or revises the narrative summarizing the evidence found in the literature. American College of Radiology (ACR) staff drafts an evidence table based on the analysis of the selected literature. These tables rate the study quality for each article included in the narrative.

The expert panel reviews the narrative, evidence table and the supporting literature for each of the topic-variant combinations and assigns an appropriateness rating for each procedure listed in the variant table(s). Each individual panel member assigns a rating based on his/her interpretation of the available evidence.

More information about the evidence table development process can be found in the ACR Appropriateness Criteria® Evidence Table Development document (see the "Availability of Companion Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

Rating Appropriateness

The American College of Radiology (ACR) Appropriateness Criteria (AC) methodology is based on the RAND Appropriateness Method. The appropriateness ratings for each of the procedures or treatments included in the AC topics are determined using a modified Delphi method. A series of surveys are conducted to elicit each panelist's expert interpretation of the evidence, based on the available data, regarding the appropriateness of an imaging or therapeutic procedure for a specific clinical scenario. The expert panel members review the evidence presented and assess the risks or harms of doing the procedure balanced with the benefits of performing the procedure. The direct or indirect costs of a procedure are not considered as a risk or harm when determining appropriateness. When the evidence for a specific topic and variant is uncertain or incomplete, expert opinion may supplement the available evidence or may be the sole source for assessing the appropriateness.

The appropriateness is represented on an ordinal scale that uses integers from 1 to 9 grouped into three categories: 1, 2, or 3 are in the category "usually not appropriate" where the harms of doing the procedure outweigh the benefits; and 7, 8, or 9 are in the category "usually appropriate" where the benefits of doing a procedure outweigh the harms or risks. The middle category, designated "may be appropriate," is represented by 4, 5, or 6 on the scale. The middle category is when the risks and benefits are equivocal or unclear, the dispersion of the individual ratings from the group median rating is too large (i.e., disagreement), the evidence is contradictory or unclear, or there are special circumstances or subpopulations which could influence the risks or benefits that are embedded in the variant.

The ratings assigned by each panel member are presented in a table displaying the frequency distribution of the ratings without identifying which members provided any particular rating. To determine the panel's recommendation, the rating category that contains the median group rating without disagreement is selected. This may be determined after either the first or second rating round. If there is disagreement after the second rating round, the recommendation is "May be appropriate."

This modified Delphi method enables each	anelist to articulate his or her individual interpretations of the evidence or expert of	pinion without
excessive influence from fellow panelists in	simple, standardized, and economical process. For additional information on the	ratings process see
the Rating Round Information	document.	
Additional methodology documents, includi	g a more detailed explanation of the complete topic development process and all	ACR AC topics can
be found on the ACR Web site	(see also the "Availability of Companion Documents" field).	

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

- Screening high-risk women with breast magnetic resonance imaging (MRI) is cost-effective and the cost-effectiveness of screening MRI
 increases with increasing breast cancer risk.
- Screening ultrasound (US) is indicated in high-risk patients who cannot tolerate MRI. Supplemental screening with US for women with
 intermediate risk and dense breasts is an option to increase cancer detection. However, hand-held US screening by the radiologist has a
 high false-positive rate and is time-consuming. Therefore, this may not be a cost-effective practice. The balance between cancer detection
 and the risk of a false positive result should be considered by women and their health care providers when considering the use of screening
 US or other ancillary screening examinations.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The recommendations are based on analysis of the current medical evidence literature and the application of the RAND/UCLA appropriateness method and expert panel consensus.

Summary of Evidence

Of the 52 references cited in the ACR Appropriateness Criteria® Breast Cancer Screening document, all of them are categorized as diagnostic references including 9 well designed studies, 7 good quality studies, and 21 quality studies that may have design limitations. There are 13 references that may not be useful as primary evidence. There are 2 references that are meta-analysis studies.

While there are references that report on studies with design limitations, 16 well designed or good quality studies provide good evidence.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Mammography is the only method of screening for breast cancer shown to decrease mortality.
- Several studies confirm that in a screening setting, cancer detection rate is increased with use of digital breast tomosynthesis (DBT)

- compared to two-dimensional (2-D) mammography alone. Additionally, the rate of recall for benign findings (false positives) can be decreased. Some authors found these advantages to be especially pronounced in women under age 50, in those with dense breasts, and with lesion types including spiculated masses and asymmetries.
- Breast magnetic resonance imaging (MRI) in high-risk women has been shown to have a higher sensitivity than mammography, and the
 combination of mammography and MRI in this population has the highest sensitivity. In a high-risk population, MRI and mammography
 combined have a higher sensitivity (92.7%) than ultrasound (US) and mammography combined (52%). Screening high-risk women with
 breast MRI is cost-effective and the cost-effectiveness of screening MRI increases with increasing breast cancer risk.

Potential Harms

- · Potential for false-positive findings
- Hand-held ultrasound (US) screening by the radiologist has a high false-positive rate and is time-consuming.

Relative Radiation Level Information

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level (RRL) indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, both because of organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared to those specified for adults. Additional information regarding radiation dose assessment for imaging examinations can be found in the American College of Radiology (ACR)

Appropriateness Criteria® Radiation Dose Assessment Introduction document (see the "Availability of Companion Documents" field).

Qualifying Statements

Qualifying Statements

- The American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.
- ACR seeks and encourages collaboration with other organizations on the development of the ACR Appropriateness Criteria through society
 representation on expert panels. Participation by representatives from collaborating societies on the expert panel does not necessarily imply
 society endorsement of the final document.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report

Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Mainiero MB, Bailey L, D'Orsi C, Green ED, Holbrook AI, Lee SJ, Lourenco AP, Moy L, Sepulveda KA, Slanetz PJ, Trikha S, Yepes MM, Newell MS, Expert Panel on Breast Imaging. ACR Appropriateness Criteria® breast cancer screening. Reston (VA): American College of Radiology (ACR); 2016. 7 p. [52 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2016

Guideline Developer(s)

American College of Radiology - Medical Specialty Society

Source(s) of Funding

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

Guideline Committee

Committee on Appropriateness Criteria, Expert Panel on Breast Imaging

Composition of Group That Authored the Guideline

Panel Members: Martha B. Mainiero, MD (*Principal Author*); Lisa Bailey, MD; Carl D'Orsi, MD; Edward D. Green, MD; Anna I. Holbrook, MD; Su-Ju Lee, MD; Ana P. Lourenco, MD; Linda Moy, MD; Karla A. Sepulveda, MD; Priscilla J. Slanetz, MD, MPH; Sunita Trikha, MD; Monica M. Yepes, MD; Mary S. Newell, MD (*Panel Chair*)

Financial Disclosures/Conflicts of Interest

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Mainiero MB, Lourenco A, Mahoney MC, Newell MS, Bailey L, Barke LD, D'Orsi C, Harvey JA, Hayes MK, Huynh PT, Jokich PM, Lee S, Lehman CD, Mankoff DA, Nepute JA, Patel SB, Reynolds HE, Sutherland ML, Haffty BG, Expert Panel on Breast Imaging. ACR Appropriateness Criteria® breast cancer screening. [online publication]. Reston (VA): American College of Radiology (ACR); 2012. 5 p. [28 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability	
Available from the American College of Radiology (ACR) Web site	

Availability of Companion Documents

The following are available:

•	ACR Appropriateness Criteria®. Overview. Reston (VA): American College of Radiology; 2015 Oct. 3 p. Available from the American
	College of Radiology (ACR) Web site
•	ACR Appropriateness Criteria®. Literature search process. Reston (VA): American College of Radiology; 2015 Feb. 1 p. Available from
	the ACR Web site
•	ACR Appropriateness Criteria®. Evidence table development. Reston (VA): American College of Radiology; 2015 Nov. 5 p. Available
	from the ACR Web site
•	ACR Appropriateness Criteria®. Topic development process. Reston (VA): American College of Radiology; 2015 Nov. 2 p. Available
	from the ACR Web site
•	ACR Appropriateness Criteria®. Rating round information. Reston (VA): American College of Radiology; 2015 Apr. 5 p. Available from
	the ACR Web site
•	ACR Appropriateness Criteria®. Radiation dose assessment introduction. Reston (VA): American College of Radiology; 2015 Sep. 3 p.
	Available from the ACR Web site
•	ACR Appropriateness Criteria®. Manual on contrast media. Reston (VA): American College of Radiology; 2016. 128 p. Available from
	the ACR Web site
•	ACR Appropriateness Criteria®. Procedure information. Reston (VA): American College of Radiology; 2016 May. 2 p. Available from the
	ACR Web site
•	ACR Appropriateness Criteria® breast cancer screening. Evidence table. Reston (VA): American College of Radiology; 2016. 35 p.
	Available from the ACR Web site
•	ACR Appropriateness Criteria® breast cancer screening. Literature search. Reston (VA): American College of Radiology; 2016. 1 p.
	Available from the ACR Web site

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on August 21, 2012. This summary was updated by ECRI Institute on September 14, 2016.

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